MULTIPLE HEMOCLIP SYSTEM FOR AN ENDOSCOPE

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Patent Application No. 60/347,832, filed on October 24, 2001.

FIELD OF THE INVENTION

The present invention relates to a system for clipping body tissue, such as a system for introducing a clip for hemostasis ("hemoclip") endoscopically in the GI tract.

BACKGROUND OF THE INVENTION

One known system for introducing a hemoclip endoscopically is shown in U.S. Patent No. 3,958,576 assigned to Olympus Optical Co. Ltd. of Japan. See also Japanese Patent Publication No. 04102450 and U.S. Patent No. 5,766,189. Each of these devices is used to insert a single clip, and includes a series of mechanical members to insert, eject and close or clamp the clip at a desired location, such as for hemostasis in the GI tract.

SUMMARY OF THE INVENTION

The present invention provides an improved hemoclip system. In one aspect of the invention multiple clips can be applied internally by way of a conventional endoscope without removal and reinsertion of a clip-retaining member. The system provides good control of the rotated position of a clip, with little backlash, for convenient and reliable placement of a clip or clips.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same become better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIGURE 1 is an enlarged side elevation of the distal portion of a multiple hemoclip system for an endoscope in accordance with the present invention with parts shown in section;

FIGURE 2 is a distal end elevation of the device of FIGURE 1;

FIGURE 3 is a transverse section along line 3--3 of FIGURE 1, with parts removed;

FIGURE 4 is a top plan of the distal end portion of the device with parts shown in section;

FIGURE 5 is a top perspective of a hemoclip usable in the system of the present invention;

FIGURE 6 is a top perspective of a second embodiment of a hemoclip usable in the system of the present invention;

FIGURE 7 is a top perspective of a third embodiment of a hemoclip usable in the system of the present invention;

FIGURE 8 is a side elevation of a fourth embodiment of a hemoclip usable in the system of the present invention;

FIGURE 9 is a vertical section along line 9--9 of FIGURE 5;

FIGURE 10 is a vertical section corresponding to FIGURE 9 showing aspects of an alternative embodiment of a hemoclip usable in the system of the present invention;

FIGURE 11 is a vertical section corresponding to FIGURE 9 showing aspects of a further embodiment of a hemoclip usable in the system of the present invention;

FIGURE 12 is a diagrammatic top perspective of the proximate portion of a multiple hemoclip system for an endoscope in accordance with the present invention;

FIGURE 13 is a side elevation of the proximate portion shown in FIGURE 12, with parts broken away;

FIGURE 14 is a top plan of a second embodiment of a proximate portion of a multiple hemoclip system in accordance with the present invention, with parts broken away;

FIGURE 15 is a top plan of a third embodiment of a proximate portion for a system in accordance with the present invention, with parts broken away;

FIGURE 16 is a top plan of a fourth embodiment of proximate portion for a system in accordance with the present invention, with parts broken away; and

FIGURE 17 is a top plan of a fifth embodiment of a proximate portion for a system in accordance with the present invention, with parts broken away.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to FIGURES 1-4, a hemoclip system 10 in accordance with the present invention includes an elongated outer tube or shaft 12 which may be inserted through a conventional scope for positioning a distal, clip-carrying portion 14 of the shaft at a desired location of the body, such as a location of bleeding to be clamped. Such elongated outer tube or shaft 12 can be manufactured from an extruded biocompatible polymer or other suitable material. The proximate end portion of the outer shaft connects to a handle as described below with reference to FIGURES 12-17 for external control of the relatively movable component parts of the distal portion 14.

An inner shaft 16 is slideably received within the outer shaft 12, and also may be manufactured from an extruded biocompatible polymer or other suitable material. The longitudinal position of the inner shaft 16 relative to the outer shaft 12 can be adjusted.

The cross-sectional shape of the major portion of the inner shaft 16 is best seen in FIGURE 3. A generally rectangular bore or cavity 18 is sized for receiving spring clips 20 of the type described in more detail below. To prevent stretching of the inner shaft, support wires 22 can be embedded in it at opposite sides of the central cavity or recess 18.

The cavity 18 is shaped for reception of spring clips 20. Such clips fit close within the cavity 18 but are freely slideable therein. In general, several clips are preloaded in the distal end of the inner shaft, such as three or more clips placed end to end. The clips are dispensed, in part, by a pusher block 24 received in the recess 18 proximate to the clips. The pusher block can be moved distally and proximally by manipulation of an attached core wire 26. Wire 26 extends through the inner shaft 16 and is slidable therein.

The clips 20 can be manufactured from a metal with spring and/or memory properties, such as stainless steel or Nitinol. With reference to FIGURE 5, the basic shape is a thin band plate, bent toward its center or web 28 to form a long U with elongated opposing jaws 30. The ends of the jaws are bent inward to form teeth 32 that face each other. The inner ends of the teeth can be sharpened to form grabbing hooks.

Returning to FIGURES 1 and 2, a clip opener component 34 is secured at the distal end of the inner shaft 16, such as by attachment to the strengthening wires 22 (shown in the cross-section of FIGURE 3). Such wires preferably extend the full length of the inner shaft. The clip opener includes a continuous shell 36 at its proximate end and two side pieces 38 at its distal end. As seen in FIGURE 4, the proximate portion or shell 36 tapers inward at opposite sides 37 (this tapering and other dimensions are exaggerated in the drawings for ease of illustration and description). The distal or leading ends of the clip jaws are similarly tapered. A clip 20 is "loaded" by forcing it forward, using the pusher block 24. This has the effect of wedging the side pieces 38 apart until the proximate or trailing end of the clip clears the tapered sides 37. After a short travel of the clip distally, the opening between the clip jaws formed by the teeth 32 engage the distal end portions of the side pieces 38 which project part way into the path that a clip follows when driven forward by the clip pusher 24. See, for example, the position of the side pieces 38 in FIGURE 2. The adjacent edges of the side pieces 38 are spaced apart transversely but are close enough together so as to be engaged by the tapered leading ends of the clip 20. Each side piece has proximate wedge surfaces 40 (FIGURE 1) angled outward from the center line of the device and configured such that the distal ends of the clip jaws are wedged apart when the pusher block moves the clip against the opener surfaces 40. Consequently, as a clip is forced forward along the cavity 18 of the inner shaft 16, the clip teeth 32 and jaws 30 are wedged apart to the condition illustrated at the right of FIGURE 1, contrary to the natural memory or spring characteristics of the clip. This action tends to spread the side pieces 38 apart until the central portion or web 28 of the clip fits within an intermediate cavity portion 42 of the clip opener 34. When this position is reached, the clip is reliably held in the clip opener with its jaws open.

The opened clip can be moved by manipulation of the outer shaft or tube 12, and can be rotated by manipulation of the inner tube or shaft 16. When a desired site and orientation are reached, such as a bleeding site, the clip can be ejected by withdrawing the inner shaft 16 relative to the outer shaft 12. With reference to FIGURE 1, projections 44 on the outer sides of the clip jaws 30 are positioned to engage against a metal collar 46 provided at the end of the outer shaft 12. With reference to FIGURE 2, as the inner shaft, including clip opener 34, is retracted within the outer tube, the opener side pieces 38 are

wedged apart, in the direction of the arrows 48. In addition, the clip edges can have weakening nicks 50 (shown only in FIGURE 2) that allow the metal of the jaws to bend inward as the jaws move past the opener side pieces 38, until the clip is released and its teeth 32 move toward each other to clamp the tissue at the desired site, due to the inherent spring or memory characteristics of the clip. After dispensing of one clip, the next clip can be moved into position by manipulation of the core wire 26 and attached pusher 24.

With reference to FIGURE 3, the outer periphery of the inner shaft 16 can have equally spaced ribs 52 for ease in sliding along the inner periphery of the outer shaft 12. The shafts and core wire 26 can be curved or bent during use, depending on the application.

Different clip geometries may be used, as illustrated in FIGURES 5-11. Preferably the clips are quite wide, at least one millimeter, for maximum spring force. With reference to FIGURE 6, one of the teeth 32 can form a sharpened angular projection shaped to be received in a corresponding angular recess of the other tooth 32. The web end 28 of the clip can include a circular or helical wire spring member. With reference to FIGURE 7, the web portion 28 of the clip can be narrower than the main body portion of the jaws 30, to allow some pivoting movement of an open clip when in the position at the right of FIGURE 2, it being understood that the narrowed portion of the clip web 28 would extend beyond the distal end of the outer shaft. In that case, the shoulders formed between the web 28 and jaws 30 could be positioned to substitute for the projections 44. With reference to FIGURE 8, closing force for the clip 20 can be achieved or augmented by a separate elastic band 52. One or more of the clip components can be bioabsorbable, so that the clip would automatically be released over time. The clip jaws 30 can be of rectangular cross-section (FIGURE 9) or can be arcuate (FIGURE 10) or angled (FIGURE 11) for increased rigidity.

With reference to FIGURES 12 and 13, the proximate portion 54 of the multiple hemoclip system in accordance with the present invention can be in the form of a handle having separate components for positioning the outer shaft 12 and manipulating the inner shaft 16 and core wire 26 connected to the clip opener and pusher, respectively. The parts are shown diagrammatically. The outer shaft 12 is coupled to a larger fitting 56 leading to a bracket portion 58 that can more easily be grasped and positioned by a user. The inner shaft 16 is coupled to a proximate extension 60 leading to a finger hole 62.

Most of the extension 60 is cylindrical, but an operating knob 64 is journaled on a short noncylindrical portion 66 of the extension. The knob can be turned to rotate the inner shaft, but is slideable along the noncylindrical portion 66. Sliding movement of the extension relative to the knob 64 is limited by stops 68 at both sides. Since the knob is held within the bracket 58, stops 68 define the maximum travel of the inner shaft 16 inside the outer shaft 12.

The core wire 26 is coupled to a sliding spool 70. The spool is moveable fore and aft (distally and proximally) along the extension 60, for moving the core wire and attached clip pusher relative to the inner shaft 16. Thus, the proximate portion 54 can be manipulated to position a clip adjacent to a site to be clamped, whereupon the spool 70 is moved distally to slide the core wire 26 and clip pusher 24 sufficiently to position the distal most clip as shown at the right of FIGURE 1. Knob 64 can be used to rotate the inner shaft to orient the clip as desired. Only a short relative movement of the inner and outer shafts is required to eject the clip, which will relax toward its closed position to apply a clamping force at the desired site. Thereafter, the device need not be removed and reloaded. Rather, the next clip can be moved forward and the process repeated to secure another clip. Removal of the distal portion of the multiple hemoclip system is not required until the supply of preloaded clips has been exhausted.

Other proximate operating mechanisms can be used. In the embodiment of FIGURE 14, the inner shaft 16 is coupled to the long, cylindrical extension 60 leading to the finger hole 62, as in the previously described embodiment. Also, knob 64 is journaled on, and slideable along, the non-circular portion 66, with such sliding movement being limited by stops 68. However, in the embodiment of FIGURE 14, the fitting 56 continues to and is affixed to the spool 70. Knob 64 has opposite sides that project through openings in the fitting or housing 56. Relative movement of the extension 60, such as by use of the finger hole 62, and the spool 70 results in corresponding relative movement of the inner shaft 16 and outer shaft 12.

In the embodiment of FIGURE 14, the core wire 26 connects to a slide mechanism having an external operating button 72 slideably mounted on the spool structure 70. Indicia 74 adjacent to the button 72 indicate the position of the pusher block carried by the core wire 26 at its distal end. Thus, by viewing the position of the

button 72 relative to the indicia 74, a user will know the position of the clips at the distal end and also the number of clips remaining.

The embodiment of FIGURE 15 is identical to the embodiment of FIGURE 14 except for the mechanism for moving the core wire 26. In this embodiment, the spool portion 70 carries a rotatable dial 76 having indicia 78. The core wire 26 connects to or is wrapped around an internal segment of the dial such that rotation of the dial moves the core wire 26 (and attached clip pusher) inside the inner shaft 16. The indicia 78 can be used to determine the position of the clips at the distal end and/or the number of clips remaining to be dispensed.

In the embodiments of FIGURES 16 and 17, the fitting 56 connected to the outer shaft 12 is identical to that used in the embodiment of FIGURES 12 and 13, including the bracket portions 58. In addition, the inner shaft 16 connects to the extension 60, with a non-circular segment 66 on which the knob 64 is journaled, and stops 68 limiting the relative movement of the inner and outer shafts. In the embodiment of FIGURE 16, however, the spool section 70 is fixed to the extension 60. Core wire 26 is moved relative to the spool (and, consequently, relative to the inner shaft) by a slide operating mechanism of the type described above with reference to FIGURE 14. The external button 72 is slideable lengthwise of component 70 for moving the core wire 26, and indicia 74 can be used to determine the position of the clips and the number of clips remaining.

The embodiment of FIGURE 17 is identical to the embodiment of FIGURE 16 except for the mechanism for moving the core wire 26. In the FIGURE 17 embodiment, a dial mechanism of the type described above with reference to FIGURE 15 is used. Component 70 is fixed to the inner shaft extension 60. Indicia 78 on the dial 76 indicate the position of the clips and the number of clips remaining.

While the preferred embodiment of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the spirit and scope of the invention.